REMARKS

Amendment to the Specification

The specification has been amended to add the priority information necessary to comply with 35 U.S.C. § 119(e) and 37 C.F.R. § 1.78.

Comments Regarding Restriction Requirement

Applicants hereby elect, with traverse, to prosecute Group XX, which corresponds to newly added claims 23-34 drawn to polynucleotides. Newly added claims 23-34 replace original claims 3-13, and are drawn to substantially the same invention, but are of a different scope.

The unity of invention standard *must* be applied in national stage applications

Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides:

> ... [W]hen the Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111....
>
> In applying PCT Rule 13.2 to ... national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2....

Id at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

> Examiners are reminded that unity of invention (not restriction) practice is applicable ... in national stage (filed under 35 U.S.C. 371) applications.

Id at page 1800-149, column 1.

Specific provisions of the Administrative Regulations Under the PCT and the corresponding provisions of the MPEP strongly support a finding of unity of invention among all of the claims in the present case

Unity of Invention is accepted between claims to polypeptides and claims to the polynucleotides which encode them

Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT provides that unity of invention is accepted between a protein and the polynucleotide that encodes it:

> *Example 17*
> Claim 1: Protein X.
> Claim 2: DNA sequence encoding protein X.
> Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

Applicants, therefore, request that the Examiner withdraw the Restriction Requirement at least with respect to claims 21, 22, 35, and 36 of Group V, and examine those claims together with the elected polynucleotide claims of Group XX. Applicants believe unity of invention exists for claims drawn to the polypeptide sequence of SEQ ID NO:6 (*i.e.*, claims 21, 22, 35, and 36) and claims drawn to the elected polynucleotide sequence of SEQ ID NO:22 which encodes SEQ ID NO:6 (*i.e.*, claims 23-34) based on the rules concerning unity of invention under the Patent Cooperation Treaty.

Unity of invention exists with respect to dependent claims in the same claim category as the independent claim from which they depend

MPEP section 1850(A) and 1893.03(d), which recite the provisions of paragraph (c) of Part 1 (entitled "Instructions Concerning Unity of Invention") of Annex B (entitled "Unity of Invention") to the Administrative Instructions Under the PCT, provides:

> **(A) Independent and Dependent Claims.**
>
> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).
>
> (i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, **it does not matter if a dependent claim itself contains a further invention**.... (Emphasis added.)

See MPEP section 1850(A) at page 1800-61. See also MPEP Appendix AI at page 53.

Accordingly, new claims 43-45, drawn to antibodies, should also be examined together with the claims drawn to polypeptides from which they depend. The claimed antibodies are limited by "all the features of another claim," in that the claimed antibodies specifically bind to a polypeptide of claim 21. Moreover, claims 22-27, 35, 36, and 43-45, all of which depend from claim 21, are all directed to compositions of matter, *i.e.,* to products. Further, as discussed above, there is unity of invention among claims 21, 23, and 30.

Unity of invention exists among all of Applicants' claims as they relate to SEQ ID NO:6 and SEQ ID NO:22

MPEP 1850 provides:

> Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Id at page 800-61.

MPEP 1893.03(d) similarly provides:

> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

Id at page 1800-149.

In the present case, unity of invention exists among all of Applicants' claims. The sequences of the claimed polypeptides and the sequences of the claimed polynucleotides encoding those polypeptides are corresponding technical features which are common to all of Applicants claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a single general inventive concept, and

Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application.

The sequences of SEQ ID NO:6 and SEQ ID NO:22 are corresponding technical features that are common to all of Applicants' claims and that serve to technically interrelate them

The sequences of the claimed polypeptides and corresponding polynucleotides are common to all of Applicants' claims, given that each claim refers to one or both either explicitly or implicitly, by virtue of depending from a claim which makes an explicit reference to the sequences of the claimed polypeptides or claimed polynucleotides.

Moreover, the sequences of the claimed polypeptides and corresponding polynucleotides serve to technically interrelate all of Applicants' claims. Applicants' composition of matter claims 21-27, 30, 31, 35, 36, and 43-45) are drawn to either the polypeptides or polynucleotides themselves (21 and 22, drawn to polypeptides, and 23-25, 30, and 31drawn to polynucleotides), to compositions of matter which comprise the polypeptides or polynucleotides as one element (26 and 27, drawn to recombinant polynucleotides and transformed cells, respectively, and 35 and 36, drawn to pharmaceutical compositions), or to compositions of matter wherein the sequences of the claimed polypeptides functionally limit the claimed subject matter (Claims 43-45, drawn to an antibody which specifically binds a polypeptide of claim 21).

In Applicants' method claims 28-29, 32-34, and 37-40), the claimed polypeptides or polynucleotides serve as either the product of the claimed method (claims 28-29, drawn to methods of polypeptide production) and/or as a reagent for performing the method (claims 32-34 drawn to methods of detecting a target polynucleotide in a sample; claim 38, drawn to a method of screening for a compound that specifically binds to a polypeptide of claim 21; claim 39, drawn to a method of screening a compound for effectiveness in altering expression of a polynucleotide of claim 25; and claim 40, drawn to a method of assessing toxicity of a test compound using a polynucleotide of claim 30).

Therefore, the sequences of the claimed polypeptides and polynucleotides are corresponding technical features which are common to all of Applicants' claims, and which serve to technically interrelate them.

Minimal burden to search new claims 39 and 40, drawn to methods of using the elected polynucleotides, and claims 41 and 42, drawn to arrays containing the elected polynucleotides

Applicants also respectfully submit that there is minimal additional burden on the Examiner to examine newly added claims 39 and 40, which are drawn to methods of using the elected polynucleotides, and newly added claims 41 and 42, which are drawn to microarrays using the elected polynucleotides. The search required to identify prior art relevant to these claims should substantially overlap with that required for examination of the elected polynucleotides of Group XX.

Obligation to rejoin method claims upon allowance of product claims under U.S. practice

The Examiner is reminded that claims 32-34, 39, and 40, drawn to methods of using the elected polynucleotides of Group XX should be rejoined per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products. Applicants request that claims 32-34, 39, and 40 be rejoined and examined upon allowance of the claims drawn to the polynucleotides of Group XX.

It is noted that, while Applicants have canceled and not repeated new versions of the claims of Groups XLVII-LXXVI, corresponding to original claims 17, 18, and 20 drawn to agonist, antagonists, and a method of treating a disorder by administering an antagonist. Applicants expressly assert that these claims have been canceled for reasons relating to cost and efficiency of prosecution of the presently elected claims, and not for reasons relating to patentability. Applicants further expressly reserve the right to pursue the subject matter of those canceled claims, or any other subject matter disclosed but not herein claimed, in a later continuation or divisional application.

Please charge Deposit Account No. **09-0108** in the amount of **$90.00**, as set forth in the enclosed transmittal letter. If the USPTO determines that an additional fee is necessary, please charge any required fee to Deposit Account No. **09-0108.**

Respectfully submitted,

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